UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, and WISCONSIN; the DISTRICT OF COLUMBIA, the CITY OF CHICAGO, and the CITY OF NEW YORK *ex rel.*, and OSWALD BILOTTA, Plaintiffs, -against- NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	**11 Civ. 0071 (PGG)**

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION'S MOTION TO EXCLUDE THE TESTIMONY OF VIRGINIA B. EVANS

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Defendant Novartis Pharmaceuticals Corporation ("NPC") respectfully submits this motion to exclude the expert testimony of Virginia B. Evans.

PRELIMINARY STATEMENT

The Government has offered Virginia Evans as a purported expert in pharmaceutical compliance. Her August 14, 2017 Report (the "Report")[1] consists entirely of Ms. Evans summarizing select portions of the factual evidence in narrative fashion and making conclusory and generalized assertions as to whether NPC's compliance program (over a nearly ten-year period) was "effective". Ms. Evans does not link her assertions regarding "effectiveness" to objective, let alone contemporaneous, standards. Nor does Ms. Evans set forth any other methodology for reaching her conclusions, and therefore her opinions should be excluded in their entirety.

LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence allows expert testimony only if (1) "the testimony is based on sufficient facts or data"; (2) "the testimony is the product of reliable principles and methods"; and (3) "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. Additionally, "the expert's scientific, technical, or other specialized knowledge" must "help the trier of fact to understand the evidence or to determine a fact in issue". Id. "[T]he proponent of expert testimony has the burden of establishing by a preponderance of the evidence that the admissibility requirements of Rule 702

[1] (Declaration of Benjamin Gruenstein in Support of Novartis Pharmaceuticals Corporation's Motions To Exclude the Proffered Opinions of Plaintiffs' Experts ("Gruenstein Decl."), Exhibit ("Ex.") 1, Expert Report of Virginia B. Evans (hereinafter "Evans Rep.").)

are satisfied." United States v. Williams, 506 F.3d 151, 160 (2d Cir. 2007); Baker v. Urban Outfitters, Inc., 254 F. Supp. 2d 346, 353 (S.D.N.Y. 2003) (excluding report and testimony).

In order for expert testimony to be deemed reliable, it must be reliable at every step; "any step that renders the analysis unreliable . . . renders the expert's testimony inadmissible". Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 267 (2d Cir. 2002). "[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, Daubert and Rule 702 mandate the exclusion of that unreliable opinion testimony." Id. at 266.

Another "fundamental" requirement of Rule 702 is that the proffered testimony "assist the trier of fact". In re Rezulin Prods. Liab. Litig., 309 F. Supp. 2d 531, 540 (S.D.N.Y. 2004). "An expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based on record evidence . . . experts who 'merely recite what is on the face of a document produced during discovery' do 'no more than that which the finder of fact could him or herself do,' and such experts' reports 'may be precluded on that basis alone.'" Anderson News, L.L.C. v. Am. Media Inc., No. 09 Civ. 2227(PAC), 2015 WL 5003528, at *2 (S.D.N.Y. Aug. 20, 2015).

ARGUMENT

I. THE REPORT IS NOT RELIABLE BECAUSE MS. EVANS DOES NOT PRESENT A METHODOLOGY.

Ms. Evans's report, which purports to opine on the effectiveness of NPC's compliance program, is not reliable because it fails to articulate a methodology for determining when a compliance program is "effective", let alone apply any such methodology to the facts of this case.

Expert opinions are deemed unreliable where the expert "presents no methodology or analysis to support her assertion". Scentsational Techs., LLC v. Pepsi, Inc., 13-CV-8645 (KBF), 2018 WL 1889763, at *6 (S.D.N.Y. Apr. 18, 2018); see also Donnelly v. Ford Motor Co., 80 F. Supp. 2d 45, 49 (E.D.N.Y. 1999) ("Subjecting [expert's] opinions to Daubert scrutiny exposes immediately their unreliability, for nothing in his report explains the reasoning or methodology by which he reaches them.").

Here, Ms. Evans does not articulate a methodology for determining that a compliance program is effective. She offers no objective standard for measuring "effectiveness", such as regulatory guidance or industry practice, nor does she offer her own criteria. Although she refers generally to three guidelines at the beginning of her report (OIG's 2003 Compliance Program Guidelines for Pharmaceutical Manufacturers, U.S. Sentencing Commission's Sentencing Guidelines for Organizations and the PhRMA Code) (see Evans Rep. at 3), these sources do not themselves set forth a method for concluding compliance effectiveness,[2] and Ms. Evans does not herself explain how she used these sources in reaching her opinions. Instead, she simply identifies a number of things that NPC's compliance program "should" have done "better", without offering any basis for her conclusions (for example, tying the supposed deficiencies to the guidelines she references in the beginning of her Report or to what other pharmaceutical companies were doing at the time).

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[2] (Gruenstein Decl. Ex. 11, U.S. Sentencing Commission's Sentencing Guidelines for Organizations; Ex. 12, 2002 PhRMA Code; Ex. 13, OIG Compliance Program Guidelines for Pharmaceutical Manufacturers; & Ex. 14, 2009 PhRMA Code.) These guidelines are just that—guidelines—and, in fact, they do not even address most of the NPC compliance weaknesses alleged in the Report. For example, none of the guidelines discusses the propriety of a doctor attending multiple promotional programs related to the same drug.

In fact, it is not clear from the Report which of Ms. Evans's conclusions relate to actions NPC should have taken as a "best practice", versus actions which supposedly rendered its compliance program "ineffective". This is a critical distinction because as Ms. Evans herself acknowledges, just because a practice could be improved, does not mean it is deficient: "Q. . . . [S]aying that something was not the best practice, that's not equivalent to saying that it was ineffective, was it? A. No, that's correct." (Gruenstein Decl. Ex. 2, Evans Deposition Transcript Excerpts (hereinafter "Evans Dep. Tr.") at 117:24-118:5.)

Similarly, although Ms. Evans recognizes that NPC's compliance program had some strengths, she does not explain how the strengths should be measured against the weaknesses to draw a conclusion on effectiveness.[3] This prevents a jury from considering the validity of Ms. Evans's testimony and instead improperly requires jurors to "take her word for it". See Fed. R. Evid. 702, advisory committee's note to 2000 amendment ("The trial court's gatekeeping function requires more than simply 'taking the expert's word for it'. . . . The more subjective and controversial the expert's inquiry, the more likely the testimony should be excluded as unreliable.").

Furthermore, assuming for purposes of argument only that Ms. Evans's general references to certain guidelines, such as those in the beginning of her Report, can be considered a "methodology", her failure to apply any such methodology to the facts of this case separately renders her opinions unreliable.[4] Deutsch v. Novartis Pharm. Corp., 768 F. Supp. 2d 420, 466

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[3] In fact, despite stating that she is analyzing the "effectiveness" of NPC's compliance program, she herself is unable to state when a control becomes "effective", but instead can only identify ways in which NPC's program could have been better. (Evans Dep. Tr. at 33:10-34:24.)

[4] Ms. Evans's failure to link her purported guidelines to the facts of this case is especially problematic because the guidelines evolved over time, as did NPC's compliance program. By

(E.D.N.Y. 2011) (finding "problematic" expert testimony where expert "describes her personal experience and all of the relevant FDA regulations and procedures upfront, but fails to directly tie it to her analysis. To determine whether [the expert's] opinions were anything other than ipse dixit, the Court had to continually refer back to the opening sections of her report to determine what regulation [she] was referencing or if her personal experience could serve as the basis for a particular opinion.").

Unlike the opinions of NPC's compliance expert Heidi Sorensen, who compared NPC's compliance program to relevant applicable guidance over the course of the time period at issue, Ms. Evans's opinions consist solely of reviewing the record and conclusorily opining, based on her review, on the effectiveness of NPC's compliance program. Indeed, the "risk areas" that Ms. Evans claims NPC "should have" been aware of are generally presented without citation. (See, e.g., Evans Rep. at 9 (regarding the number of attendees); 12 (regarding repeat attendance).)

She is unable to point to any literature stating that these risks were ones that NPC should have been aware of (which is not surprising considering that most of them are not referenced at all in the guidance from the applicable time periods). For example, Ms. Evans claimed at her deposition that her concept of "effectiveness" comes from "the concept of effectiveness as that is described in the Sentencing Guidelines and as is understood in the compliance industry", as well as from OIG's 2003 Compliance Program Guidelines for Pharmaceutical Manufacturers (see Evans Dep. Tr. at 12:11-21), but the Report fails to link

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making vague and general references to her guidelines, she improperly invokes them retroactively (as opposed to NPC's expert, Heidi Sorensen, who tied her analysis of the various phases of NPC's compliance program to the standards that were actually in place at the time).

NPC's "ineffectiveness" to either guideline. At her deposition, Ms. Evans was similarly unable to point to any regulatory language that supported her position. (See, e.g., id. at 90:10-25; 94:15-96:18.)

Moreover, the third source that Ms. Evans relies upon – the PhRMA code – in fact expressly contradicts some of her "conclusions". For instance, Ms. Evans faults NPC for not defining "occasional" in its policy permitting the provision of modest meals on "no more than an 'occasional basis'" (see Evans Rep. at 14), but ignores that NPC was merely using in its policy the precise language in the 2002 PhRMA Code—the sole guidance available at the time. (See Gruenstein Decl. Ex. 12, 2002 PhRMA Code, at 6.) And Ms. Evans does not explain how NPC should have defined "occasional" to eliminate the supposed risk from repeat attendance. Similarly, Ms. Evans cites the 2002 and 2009 PhRMA Codes as guidance regarding venue and entertainment policies and acknowledges that Novartis's entertainment policy from 2003-2008 is based on the 2002 PhRMA Code. (See id. at 14.) Nonetheless, she states that "[t]he rationale supporting . . . [NPC's] exceptions to the no-entertainment rule is unclear." (Id. at 15.) Ms. Evans statement is puzzling considering that the rationale supporting the exceptions is an FAQ set forth the 2002 PhRMA Code itself, which states that a speaker training weekend with "a few hours of golf" would comply with the Code.[5]

Ms. Evans also cannot rely upon her own experience to say that other compliance-minded companies were concerned about her purported "risks" during the relevant time period because she is not aware of any companies being concerned about these issues. Ms. Evans is unable to identify any companies that she advised to remedy the weaknesses that she attributes to

[5] (Gruenstein Decl. Ex. 12, 2002 PhRMA Code, at 8-9.)

Novartis or that otherwise themselves addressed those weaknesses, such as failure to restrict venue choices, failure to define modest meals, etc.[6] In short, Ms. Evans uses these supposed "weaknesses" as the basis to conclude that NPC had an ineffective compliance program, but she cannot identify contemporaneous guidelines warning of these risks or even one company that knew of the risks or sought to address them. Her current opinion that NPC should have done more to address these risks is thus groundless.

Ms. Evans's "you know it when you see it" analysis[7] is not the product of a reliable methodology and should be excluded in its entirety. See, e.g., LVL XIII Brands, Inc. v. Louis Vuitton Malletier S.A., 209 F. Supp. 3d 612 (S.D.N.Y. 2016) (aff'd 720 Fed. App'x 24 (2d Cir. 2017) (excluding expert testimony because the expert "supplied virtually no insight into the considerations that shaped his qualitative analysis. There is thus no basis on which to hold that

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[6] (See, e.g., Evans Dep. Tr. at 107:24-108:4 ("Q. Do you know, the other companies that you provided consulting advice for, do you know how they restricted venue choices during this period? A. No, I do not."); id. at 109:17-20 ("Q. Do you know whether other companies were defining 'modest' [meals] at that time? A. I do not know the answer to that question."); id. at 97:14-98:10 ("Q. Do you recall advising your clients about repeat attendance by doctors at the same program? . . . A. No I don't recall providing that guidance."); id. at 116:12-21 ("Q. So then at the top of 20, you say, 'In my opinion, sales associates should have been taken out of the speaker program—speaker selection process entirely. HCP requests for speaking engagements should have been referred elsewhere in the organization.' Do you know whether other companies were doing that at this time? A. I do not know the answer to that question."); id. at 184:15-185:24 ("Q. So are you saying that the controls around exception reports were ineffective because exception reports weren't done on a regular enough basis? A. Well, I think once that they had the opportunity to gather that information, NPC could have and should have set up an exception reporting process whereby, on a regular basis, the exception reports were brought to the attention of the compliance officer. . . . Q. Do you know whether other companies during the review period were doing exception reporting? A. I do not."); see also id. at 187:12-189:7; id. at 200:25-201:5.)

[7] Ms. Evans expressly testified that in her view whether a company has a culture of compliance is a "you know it when you see it" determination. (Evans Dep. Tr. at 31:13-16 (". . . culture of compliance is kind of difficult to—to describe, you know, you— Q. You know it when you see it? A. You know it when you see it.").)

his opinions derive from a reliable methodology."); In re M/V MSC Flaminia, 12-cv-8892, 2017 WL 3208598, at *2540 (S.D.N.Y. July 28, 2017) ("[C]onclusory opinions—often referred to as ipse dixit—fail to provide a methodology that would allow a court to assess reliability."); 24/7 Records, Inc. v. Sony Music Entm't, Inc., 514 F. Supp. 2d 571, 576 (S.D.N.Y. 2007) (excluding expert testimony on valuation when the expert "does not explain how he valued these factors nor how he assessed their relative significance. . . . Instead of applying a discernable methodology to the data before him, [the expert] appears to rely on his instinct, an approach that cannot be tested, has no known rate of error, and is not subject to any standards.").

II. THE REPORT IS NOT RELEVANT OR HELPFUL TO THE JURY BECAUSE IT CONSISTS ENTIRELY OF IMPERMISSIBLE FACTUAL NARRATION.

Instead of articulating an objective methodology and then applying it, Ms. Evans simply reviews and summarizes portions of the factual record and presents them in a way that she argues supports her conclusions. When this impermissible factual narration is stripped away, Ms. Evans's opinions regarding NPC's compliance program are conclusory (and largely unexplained). Courts routinely exclude purported expert testimony that is "merely a 'narrative of the case which a juror is equally capable of constructing'". Rezulin, 309 F. Supp. at 541, 551 ("[E]xperts should not be permitted to 'supplant the role of counsel in making argument at trial, and the role of the jury in interpreting the evidence.'"); see also Anderson News, 2015 WL 5003528, at *2. Because factual narration is not helpful to the jury, such expert opinions are considered irrelevant. Rezulin, 309 F. Supp. at 541 ("This helpfulness requirement is akin to the relevance requirement of Rule 401, which is applicable to all proffered evidence but goes beyond mere relevance because it also requires expert testimony to have a valid connection to the pertinent inquiry." (citation and quotation omitted)); see also Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 592 (1993).

In Rezulin, for example, the court excluded expert factual narratives, holding that such material should be presented through percipient witnesses and documentary evidence. The court noted that "the glosses that [the expert] interpolates into his narrative are simple inferences drawn from uncomplicated facts that serve only to buttress plaintiffs' theory of the case. . . . [The expert] 'does no more than counsel for plaintiff will do in argument, i.e., propound a particular interpretation of [defendant]'s conduct.'" Id. at 551 (emphasis added) (quoting LinkCo, Inc. v. Fujitsu Ltd., No. 00 CIV. 7242(SAS), 2002 WL 1585551, at*2 (S.D.N.Y. July 16, 2002); accord GST Telecomms., Inc. v. Irwin, 192 F.R.D. 109, 111 (S.D.N.Y. 2000) ("[T]he Court should not shift to [expert] witnesses the responsibility to give conclusory opinions and characterizations of the business conduct portrayed.").

In In re Fosamax Products Liability Litigation, plaintiffs offered an expert to opine on certain FDA regulatory requirements, Merck's interactions with the FDA and whether Merck satisfied the regulations. 645 F. Supp. 2d 164, 189 (S.D.N.Y. 2009). The court explained that "[a]t the beginning of each section, [the expert] expresses a number of opinions as to the ways in which Merck's conduct failed to measure up to standards. The sections then extensively summarize or quote the record evidence that provides the bases for her opinions." Id. (internal citation omitted). The court held that it was impermissible for the expert to "present[] a narrative of select regulatory events through the summary or selective quotation from internal Merck documents, regulatory filings, and the deposition testimony of Merck employees". Id. at 192. The court limited the expert's "commentary on any documents and exhibits in evidence . . . to explaining the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge". Id. The court did not permit the expert "to merely read,

selectively quote from, or 'regurgitate' the evidence". Id. The court also excluded opinions that were "too conclusory or insufficiently based on expertise or analysis", finding that they were "not expert opinions but mere 'bad company' testimony with marginal relevance to the issues in controversy". Id. at 191-92.

Like the expert in Fosamax, "[a]t the beginning of each section," Ms. Evans "expresses a number of opinions as to the ways in which [NPC's] conduct failed to measure up to standards. The sections then extensively summarize or quote the record evidence that provides the bases for her opinions." Id. at 189. If the Government wishes to present a factual narrative to the jury, it must do so through documents and witness testimony. See Rezulin, 309 F. Supp. 2d at 551.

The Report's factual narration is particularly unhelpful to the jury because it is not objective. First, Ms. Evans repeatedly acknowledged in her deposition that she was weighing or assessing the credibility of the evidence and drawing conclusions concerning NPC's state of mind.[8] It is well-settled law that each constitutes improper expert testimony. See, e.g., Highland Capital Mgmt. L.P. v. Schneider, 551 F. Supp. 2d 173, 180 (S.D.N.Y. 2008) ("[Expert's] opinion as to the credibility of witnesses is inadmissible"); id. at 182 ("[The expert's] belief about a

[8] (See, e.g., Evans Dep. Tr. at 74:8-75:10; 127:19-128:16; 122:17-123:6; 134:20-135:20; see also Evans Rep. at 13 ("But, in my opinion, it is also clear from the materials that NPC was aware that repeat attendance presented serious compliance risks."); Evans Dep. Tr. at 102:16-25 ("Q. Okay. But to be clear, I mean, you say, 'In my opinion it is clear from the materials that NPC was aware.' It sounds like what you're saying now is, in your—based on your review of all the documents and depositions cited in footnote 50, it seems that people at NPC were aware of this compliance risk; is that correct? . . . A. I think that's right.").)

party's state of mind is an improper subject for expert testimony and cannot be saved by couching his opinion as 'industry custom and practice.'").[9]

Second, Ms. Evans was highly selective in choosing which facts to include in her report, which is not the role of an expert. The "selection, organization and characterization of excerpts from the discovery record is 'no more than counsel . . . will do in argument.' Such cherry-picking and editorializing is exactly the type of 'factual narrative' that courts routinely exclude because it invades the province of the factfinder by merely 'regurgitating the evidence.'" In re Lyondell Chem. Co., 558 B.R. 661, 668 (S.D.N.Y. Br. 2016) (internal citations omitted).[10]

To illustrate just a few examples, Ms. Evans's discussion of repeat attendance by doctors at events is three paragraphs. (Evans Rep. at 12.) The first paragraph contains a single sentence setting forth Ms. Evans's conclusion that NPC's policies failed to control for the "serious AKS risk" presented by repeat attendance. Ms. Evans does not explain how she relied on her expertise to conclude that repeat attendance posed a "serious AKS risk", nor does she

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[9] See also Rezulin, 309 F. Supp. 2d at 546 ("[O]pinions of [] witnesses on the intent, motives or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise."); Taylor v. Evans, No. 94 Civ. 8425(CSH), 1997 WL 154010, at *1-2 (S.D.N.Y. Apr. 1, 1997) (Expert report contained "speculations on defendants' state of mind" which "would not be admissible if given by any witness—lay or expert".); LinkCo, Inc., 2002 WL 1585551, at *2 ("It is also inappropriate for [the expert] to opine on the credibility of evidence.").

[10] Federal Rule of Evidence 403 also weighs in favor of excluding Ms. Evans's Report. Permitting the jury to hear Ms. Evans's biased narration of the facts would be misleading and highly prejudicial to NPC. See In re Reserve Fund Secs. & Derivative Litig., No. 09 Civ. 4346(PGG), 2012 WL 12356742, at *2 (S.D.N.Y. Sept. 10, 2012) ("The Second Circuit has noted the uniquely important role that Rule 403 has to play in a district court's scrutiny of expert testimony, given the unique weight such evidence may have in a jury's deliberations." (internal quotation marks omitted)).

identify sources to support that conclusion. The remaining three paragraphs are entirely factual without any analysis.

Ms. Evans also devotes more than five pages to a discussion of two audits NPC conducted in 2008 and 2009. (Evans Rep. at 50-55.) She selectively focuses on the audits' worst findings, and gives NPC little credit for the remedial efforts it undertook. The entire five-page section is factual narration and contains no expert analysis.

Ms. Evans additionally relies heavily on documents relating to NPC's financial controls for speaker program spending, for example, the 2008 audit report and a report by Steven Chyung, a Vice President in NPC's Sourcing department. (See, e.g., Evans Rep. at 30-31.) Ms. Evans presents these documents as reflecting NPC's knowledge that speaker programs were improperly being used to provide kickbacks to doctors. As is clear from the face of the documents (which any juror can read), and the associated deposition testimony, they discuss NPC's efforts to ensure that its sales force was using resources effectively as a business matter. The documents do not have any bearing on NPC's compliance with laws and regulations.

Ms. Evans's selective use of the evidence is also troubling in that she often relies on irrelevant or inaccurate information in reaching her "conclusions". For example, Ms. Evans claims that members of NPC's compliance department "testified" that Martins Putenis "was not an effective compliance leader" when he was responsible for the compliance function in 2002-2005. The individuals whose testimony she cites, however, only worked for NPC after 2008, and therefore cannot have provided any insight into Mr. Putenis's work from 2002-2005. Ms. Evans also repeatedly cites instances of employee misconduct to buttress her opinions. (See, e.g., Evans Rep. at 13 n. 51; 30 nn.146-48; 65 n.373.) She rarely, however, also discusses the corresponding corrective actions that NPC took after this misconduct came to light.

When Ms. Evans's factual narration is put aside, only conclusions remain. This demonstrates that the primary purpose of her report is not to convey opinions and analysis—specialized knowledge that will help the trier of fact—but to muster all of the evidentiary record in support of her argument, much as she would have done as a prosecutor, about the alleged shortcomings of Novartis's compliance program. Accordingly, her Report is inadmissible in its entirety. See Taylor, 1997 WL 154010, at *1-2 (excluding testimony from an expert, who was an attorney, where the expert's report "was the equivalent of an attorney's closing argument" and "present[ed] a narrative of the case which a lay juror is equally capable of constructing.").

CONCLUSION

For the foregoing reasons, NPC respectfully requests that this Court exclude the testimony of Virginia Evans.

Date: September 28, 2018

Respectfully submitted,

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